

**From:** [REDACTED] (SANTE)  
**Sent:** lundi 18 janvier 2021 20:46  
**To:** [REDACTED],  
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 [REDACTED]@aemps.es'; [REDACTED] (EMA);  
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 [REDACTED] (EMA); [REDACTED]@sukl.cz'; [REDACTED]  
 [REDACTED] (EMA); [REDACTED] (EMA);  
 [REDACTED]@bfarm.de'; [REDACTED]  
 [REDACTED] (EMA); [REDACTED] - The Guild';  
 [REDACTED]@lakemedelsverket.se'  
**Cc:** [REDACTED] (SANTE); [REDACTED] (SANTE);  
 [REDACTED] (SANTE)  
**Subject:** SM/NSM group meeting -- 18 January 2021-- summary-actions-  
 group members for SM/NSM Teams group  
**Attachments:** How to join our team; Group members.xlsx; IMPD-Q SM-NSM GMP  
 v2.1.docx; Q&A classification of changes v1.1.docx; SM-NSM  
 v7.docx; IMPD changes in multiple trials v2.2-mas.docx

Dear All,

Please find below the summary of today's meeting for your comments.

COM will move its meetings from webex to Teams by 1 February. Thanks for **checking in the attached xcl if every group member from your organisation is on the list (by 29 January)**. The list will be used to create a Teams group for future calls. Instructions on how to use Teams are also attached.

I will also ask you to check if the below list of meeting participants is complete, my apologies for any accidental omission.

(QWP-CHMP), (EMA); (BWP-CHMP); (CTFG/CTEG); (EFPIA); (ACRO); (EORTC); (EuropaBio); (EUCROF); (SANTE B4);

### Outcome and actions:

- The draft table for the classification of changes to the IMPDQ was finalised to be submitted to QWP/BWP to the revision of their respective guidelines. **A few outstanding items have been flagged for additional clarifications by EFPIA**
- The draft table about the GMP implications of change of source country has been discussed, **SANTE will continue working with EFPIA on the table to be presented to this group**
- The Q&A and general table about the classification of changes was finalised. It will be submitted to CTEG for review with the aim to adopt it on 4 February for publication
  - **outstanding topics:** change of a (1) comparator (SANTE) and (2) power of attorney (EFPIA)
- Additional items that will need further discussions:
  - Recommendations with examples on how to fulfil (part I) conditions as SM or art 81.9 NSM
  - Reversion of documents to the previous (original) version in case an SM is rejected

- Draft process for SM to multiple IMPD: to be discussed at next meeting (following simulation exercise and CTEG review)

The post-meeting version of the meeting documents are attached.

Thank you for all your contribution to the preparation of this meeting as well as to the discussion today.  
Kind regards,

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**From:** ■ (SANTE)  
**Sent:** Monday, January 18, 2021 1:08 AM  
**To:** ■ <■@efpia.eu>; ■ (SANTE)  
<■@ec.europa.eu>; ■ <■@syneoshealth.com>; ■  
Eskola' <■@efpia.eu>; ■ <■@acrohealth.org>; ■  
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<■@ema.europa.eu>; ■ <■@merckgroup.com>;  
■ <■@parexel.com>; ■  
■ <■@europabio.org>; ■ <■@eortc.org>;  
<■@merck.com>; ■ <■@novartis.com>;  
<■@pfizer.com>; ■ <■@ccmo.nl>; ■  
<■@aemps.es>; ■ <■@bfarm.de>; ■ (EMA)  
<■@ema.europa.eu>; ■ (EMA) <■@ema.europa.eu>;  
■ <■@eortc.org>; ■  
<■@clinrex.com>; ■ <■@bfarm.de>;  
■ <■@sukl.cz>; ■ (EMA)  
■ <■@ema.europa.eu>; ■ @sukl.cz' <■@sukl.cz>; ■  
(EMA) <■@ema.europa.eu>; ■ (EMA)  
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' <■@roche.com>; ■ - The Guild' <■@the-guild.eu>;  
■ @lakemedelsverket.se' <■@lakemedelsverket.se>  
**Cc:** ■ (SANTE) <■@ec.europa.eu>  
**Subject:** RE: SM/NSM group meeting -- 18 January -- supporting documents with NEW comments

Dear Colleagues,

Please find attached the meeting documents with compiled additional comments from the review.

Kind regards,

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**From:** ■ (SANTE)  
**Sent:** Wednesday, January 13, 2021 12:32 AM

To: [redacted] <[\[redacted\]@efpia.eu](mailto:[redacted]@efpia.eu)>; [redacted] (SANTE)  
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 [redacted] <[\[redacted\]@merckgroup.com](mailto:[redacted]@merckgroup.com)>; [redacted]  
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 [redacted] <[\[redacted\]@ccmo.nl](mailto:[redacted]@ccmo.nl)>; [redacted] <[\[redacted\]@aemps.es](mailto:[redacted]@aemps.es)>; [redacted]  
 [redacted] <[\[redacted\]@bfarm.de](mailto:[redacted]@bfarm.de)>; [redacted] (EMA) <[\[redacted\]@ema.europa.eu](mailto:[redacted]@ema.europa.eu)>;  
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 [redacted] <[\[redacted\]@clinrex.com](mailto:[redacted]@clinrex.com)>; [redacted] <[\[redacted\]@bfarm.de](mailto:[redacted]@bfarm.de)>; [redacted]  
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 Cc: [redacted] (SANTE) [redacted] <[\[redacted\]@ec.europa.eu](mailto:[redacted]@ec.europa.eu)>  
 Subject: SM/NSM group meeting -- 18 January -- supporting documents

Dear Colleagues,

First let me I wish you all a happy and more relaxed 2021.

In preparation to our next meeting on 18 January; 12:30-16:00, please find attached the following **documents for your review** and as basis for the different discussions:

- Draft Q&A on the classification of changes to ongoing trials (COM);
- Draft process for IMPD changes in multiple trials (COM, ACRO POs, EMA);
- General SM/NSM table v6 with comments from CTEG and CTFG;
- IMPDQ SM/NSM table and table with impact of change of source country (CSC) on GMP-related documents (proposal by EFPIA based on their review of the QWP/BWP guidance documents). As an explanatory note, new 'documents/data' proposed to be added to the list of changes are in blue colour; changes proposed to existing 'documents/data' are highlighted in yellow colour.

The proposed meeting **agenda** with tentative timeslots:

- Introduction of new members in the group (12:30-12:35)
- Focused review of the IMPDQ SM/NSM table – chaired by QWP/BWP (12:35-13:45)
- GMP changes after a change to the source country (13:45-14:30)

- Draft Q&A on classification and focused review of the general SM/NSM table (14:30-15:15)
- Discussion of the process for multi-trial IMPD changes/changes to common IMPD (15:15-15:50)
- Next steps, timelines (15:50-16:00)

The **aim** of the meeting is to:

- Finalise the draft IMPDQ SM/NSM and GMP/CSC table to support QWP/BWP with their revision of the corresponding guidance documents;
- Finalise the draft general SM/NSM table and classification Q&A with the aim to present them to CTEG for adoption and publication on 4 February;
- Progress with the draft process for multi-trial IMPD changes and agree on the test scenarios for the simulation exercise.

Many thanks to EFPIA for developing the draft IMPDQ and GMP SM/NSM documents and to ACRO POs/EMA for the critical review of the draft process for multi-trial IMPD changes.

I ask you to send me any critical comments regarding the attached documents or the organisation of the meeting by Friday noon.

Please feel free distribute further this message to relevant colleagues within your organisation in case I accidentally missed to include anyone from this mailing list. Also let me know if you do have not received the webex invitation with the link to join the meeting.

Kindest regards,



- Pharmaceuticals



**European Commission**

Directorate-General for Health and Food Safety

Unit B4- Medical products: quality, safety, innovation

